JOHN D. CLINE (CA State Bar No. 237759)
One Embarcadero Center, Suite 500
San Francisco, CA 94111
Telephone: (415) 662-2260 | Facsimile: (415) 662-2263
Email: cline@johndclinelaw.com

KEVIN M. DOWNEY (Admitted Pro Hac Vice)
LANCE A. WADE (Admitted Pro Hac Vice)
SEEMA MITTAL ROPER (Admitted Pro Hac Vice)
MICHELLE CHEN (Admitted Pro Hac Vice)
WILLIAMS & CONNOLLY LLP
725 Twelfth Street, NW
Washington, DC 20005
Telephone: (202) 434-5000 | Facsimile: (202) 434-5029
Email: KDowney@wc.com; LWade@wc.com; SMRoper@wc.com; MChen@wc.com

Attorneys for Defendant ELIZABETH A. HOLMES

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. ELIZABETH HOLMES and RAMESH "SUNNY" BALWANI, Defendants.	Case No. CR-18-00258-EJD **REPLY IN FURTHER SUPPORT OF MS. HOLMES' MOTION TO COMPEL PRODUCTION OF RULE 16 DISCOVERY AND *BRADY* MATERIALS** Date: June 28, 2019 Time: 10:00 a.m. CTRM: 4, 5th Floor Hon. Edward J. Davila

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In building its case against Ms. Holmes, the United States government asked agencies of the United States to preserve all documents relating to Theranos and to grant prosecutors unfettered access to them. Those agencies readily complied. Having been granted access to ***all*** Theranos-related documents, the government "tailored its requests to these agencies to capture the documents" that it deemed "most relevant to this case." Opp'n 1. There is nothing in the record to suggest that the agencies put up the slightest resistance to these requests. But when Ms. Holmes asked in early February 2019 for six narrow categories of documents that the record shows very likely exist at these agencies, the government said no. Now—almost half a year later—the government offers a "voluntary" production of agency documents with so many qualifiers, exceptions, and loose ends that it is entirely unclear what it is agreeing to produce, or when Ms. Holmes can expect to receive the documents she needs to prepare her defense. And the agencies are frank about their reluctance to comply: having provided the prosecution with all the documents it requested to build its case, they apparently do not feel similarly obligated to search for or retrieve documents to assist Ms. Holmes.

Ninth Circuit law, however, requires full compliance with Ms. Holmes' requests because the government has knowledge of, and access to, the documents she seeks, *United States v. Santiago*, 46 F.3d 885, 894 (9th Cir. 1995), and they are material to her defense, Fed. R. Crim. P. 16(a)(1)(E). The Court should grant Ms. Holmes' motion to compel.

I. The Government Has Knowledge of, and Access to, the Requested Materials.

Ninth Circuit law on the government's Rule 16 obligations is clear: the prosecution must produce the requested agency documents if they are helpful to the defense and if the prosecution has knowledge of, and access to, them. *Santiago*, 46 F.3d at 894; *United States v. Bryan*, 868 F.2d 1032, 1036 (9th Cir. 1989). The government does not seriously engage with the rule articulated in *Santiago* and *Bryan*. It attempts to sweep aside those cases based on the identity of the agencies involved. *See* Opp'n 9. But the Ninth Circuit's rulings did not turn on the identity of the at-issue agencies but rather on the fact of the government's knowledge of, and access to, the documents. The record here unquestionably demonstrates the government's access to the requested agency documents. *See* Mot. 11-13 (FDA and CMS); *id.* 20-21 (SEC); *id.* 22-23 (CDPH). The government does not dispute—and in

many instances concedes—the key facts showing its access to the requested documents:

- In March 2017, a U.S. Postal Inspector investigating Theranos requested from the FDA access to all "[r]ecords and files maintained or created by the [FDA] concerning Theranos" and "access and ability to conduct and participate in interviews of FDA employees concerning their interactions with Theranos." Mot. Ex. 6. The FDA in response "authorized" certain of its employees "to provide the information that [the government] requested." Mot. Ex. 7; *see also* Opp'n Ex. C (letter from FDA acknowledging it had turned over "a significant number of FDA documents—over 40,000 pages—relating to Theranos" to the government).

- The government made similarly broad requests to CMS. *See* Mot. 12 n.11. CMS acknowledges that it complied with those extensive requests. *See* Opp'n Ex. D.

- The government issued identical litigation holds to the FDA and CMS in 2017, requiring preservation of "[a]ny and all communication[s] between a Theranos, Inc. employee and an [FDA/CMS] employee" as well as "[a]ny and all communication[s] between [FDA/CMS] employees concerning Theranos. Mot. Ex. 8.

- The government has included a substantial amount of FDA, CMS, and CDPH documents in its Rule 16 productions. Mot. 13, 22; *see* Opp'n 3 ("The government has already produced the vast majority of all of the materials it has obtained from [the subject agencies], and its preparing to produce the rest.").

- The SEC granted the government access to all non-public files related to the SEC's investigation of Theranos. Mot. Ex. 17. And the DOJ and SEC conducted at least 57 joint interviews in their joint investigation. Mot. 20; *see* Opp'n 12 (conceding that DOJ and SEC investigations were "coordinated"). The agencies also engaged in joint document requests and collection from third parties and freely exchanged documents throughout. *See* Opp'n 12 ("documents were shared between the criminal and civil investigations").

Any one of the above undisputed facts is dispositive proof of the government's access to the subject agencies' documents under *Santiago*. But the government's document preservation letters to FDA and CMS are particularly telling. In those letters, the same government lawyers who now disclaim any access to these agencies' documents ***ordered*** the agencies to abide by their obligations to preserve documents because "[o]nce ***a party*** reasonably anticipates litigation, it must suspend ***its*** routine document retention/destruction policy and put in place a litigation hold." Ex. 8 (emphases added). In 2017, the government held the view that these agencies were so integral to its case that they should be considered "a party" to the litigation. Now the government asserts they are agencies with "a significant degree of autonomy over [their] records and resources." Opp'n 1. Nothing about the prosecutors' relationship with the agencies, of course, has changed. The only thing that has changed is the identity of the party requesting the documents.

Rather than contest the facts demonstrating its access, the government invokes the considerable fruit of that access—FDA's "earlier production" *to the government* "of approximately 40,000 pages" of materials, Opp'n 5; CMS' prior production of "more than 260,000 pages of documents *to DOJ*," Opp'n 7; extensive joint document collection and exchange with the SEC *in their "coordinated" investigation*, Opp'n 12—as reason to deny the motion. Incredibly, the government asserts that Ms. Holmes' request is "unfair" in part because the agencies' voluntary compliance with the government's earlier requests was so comprehensive. *See* Opp'n 1; *see also* Opp'n Exs. C, D (letters from FDA and CMS, respectively, resisting full compliance on these grounds). As further explained below, *see* Part II, *infra*, the government's purported concerns about the burden of Ms. Holmes' requests on the agencies are overstated. And its conception of what fairness demands is wrong. Principles of fairness prohibit the government from making "requests to these agencies to capture the documents" it deems as "most relevant to the case," Opp'n 1, while leaving the documents Ms. Holmes would use in her defense to repose at the agencies beyond her reach. *See, e.g.*, *Bryan*, 868 F.2d at 1036 ("Limiting 'government' to the prosecution alone ***unfairly*** allows the prosecution access to documents without making them available to the defense." (emphasis added) (alteration and internal quotation marks omitted)); *see also United States v. Libby*, 429 F. Supp. 2d 1, 11 (D.D.C. 2006).

The government's admission that the agencies expended significant resources assisting the government should end the inquiry. The government nevertheless offers several halfhearted legal arguments, each of which should be rejected.

First, the government accuses Ms. Holmes of treating the government as "a monolith" and of arguing that "every government agency has automatic access to the documents of every other." Opp'n 1. That hyperbole is easily dismissed. Ms. Holmes has not asked the government to search the files of the Environmental Protection Agency or the Department of Labor, for example. She has asked the government to search for six narrow categories of documents in the files of the very same agencies whose files the government searched for documents helpful to its case. Rule 16 and *Santiago* together provide applicable limiting principles for requests for agency documents—the documents must be helpful to the defense, and the prosecution must have demonstrated access to them.

Second, the government asserts that it would be "problematic if a single, voluntary production of documents by a third party were sufficient to give the prosecution 'access' to the rest of that party's documents," and raises the specter of criminal defendants' "obtain[ing] unfettered access to victims' documents through the government." Opp'n 8. Of course, a "single, voluntary production" is not what happened here, as the agencies' protestations about the scope of their prior productions demonstrate. But *Santiago* itself demonstrates that a single request for a single document may be sufficient to establish access. *See* 46 F.3d at 893-94 (request for and receipt of one inmate's prison file is proof of access to other inmates' files). And Rule 16's materiality requirement will confine the scope of an agency's production obligations. The government's vague reference to "victims' documents" likewise is no barrier to granting Ms. Holmes' motion. Ms. Holmes seeks documents from government agencies, not from third-party "victims."

Third, the government points to boilerplate language concerning trade secret and public disclosure limitations in the FDA's letter granting it access to all Theranos-related documents at the agency to argue that its access to those documents was not "carte blanche." Opp'n 8. The government does not claim, however, that the FDA declined to produce a single document on these bases. The 40,000 pages of FDA documents the government has produced to the defense suggests that these concerns did not prevent the government from obtaining information it sought from the agency.

Fourth, although the government conspicuously avoids using the term "prosecution team" in opposition to the motion to compel, the government nonetheless argues that the agency documents are not discoverable because CMS (and, presumably, CDPH) did not "participate[] in the criminal investigation," and because the SEC and DOJ did not "exercise[] . . . authority over each other, and only the FDA-CI office participated in the criminal investigation." *Id.* at 9. As *Santiago* and *Bryan* make clear, these arguments have no purchase in the Ninth Circuit. The question is not whether these agencies were involved in the government's investigation, but whether the government obtained access to Theranos-related documents at these agencies in the course of that investigation. *Santiago*, 46 F.3d at 893-94. It unquestionably obtained such access.

Fifth, with respect to the SEC, the government suggests that it need not produce documents in

the possession of the SEC because those two agencies only "coordinated [] aspects of their investigations for the sake of efficiency." Opp'n 12. But the reason *why* the two entities decided to share evidence freely and to conduct joint witness interviews is irrelevant to whether the government has access over documents generated or acquired in the course of that investigation. The government also resorts to semantic hairsplitting over whether its investigation was "joint" or "parallel," *id.*, but it cites no Ninth Circuit authority explaining whether or how such distinctions matter in the application of the *Santiago* standard. And it tellingly does not even attempt to distinguish the Southern District of New York case cited in the motion—*United States v. Gupta*, 848 F. Supp. 2d 491 (S.D.N.Y. 2012)—which held that coordinated fact-gathering similar to what occurred here rendered an investigation "joint" and thus necessitated production of SEC documents in the criminal case. *Id.* at 494-95.

Sixth and finally, regarding CDPH, the government states the rule—acknowledged in the motion, *see* Mot. 23—that federal prosecutors generally will not be deemed to have access to state agency materials under Rule 16. Opp'n 11-12. But the government simply ignores Ms. Holmes' argument that this rule gives way in cases, like here, where the federal government has a unique degree of control over the requested documents. *See* Mot. 23 (citing *United States v. Liquid Sugars*, 158 F.R.D. 466 (E.D. Cal. 1994)). The CDPH documents Ms. Holmes seeks—records relating to the 2013 CLIA survey of Theranos—were created by CDPH in its capacity as the local enforcement arm of a comprehensive federal regulatory scheme.[1] *See* Mot. 23. The law requires CDPH to share its CLIA documentation with CMS, *see* Mot. 5-6, and the record demonstrates that this sharing occurred here. *See* Mot. Ex. 18. The fact that CMS obtained partial compliance from CDPH with the government's recent request only underscores the unique position of CDPH with respect to its federal counterpart and distinguishes this case from those cited by the government. *See* Opp'n Exs. D, E.

The government also ignores the fact that the defense relies upon *Brady*, in addition to Rule 16, as a basis for producing CDPH documents. *See* Mot. 22 (explaining that internal CDPH

[1] Federal law defines employees of state regulatory agencies such as the CDPH who are engaged in "performing survey, certification, or enforcement functions" as "employees" of the Department of Health and Human Services ("HHS") for purposes of HHS' compliance with requests for testimony by employees and production of documents in court proceedings. 45 C.F.R. § 2.2.

communications will provide necessary context to interpreting the favorable findings of the 2013 CLIA survey). The government does not dispute that CDPH possesses potential *Brady* material; it asserts only that it is "not obligated to review state" agency files at all. Opp'n 12 (internal quotation marks omitted). The government is incorrect. It must inquire for *Brady* materials at each state agency with which it "consults" during the investigation and from which it obtains documents. *United States v. Cerna*, 633 F. Supp. 2d 1053, 1059-60 (N.D. Cal. 2009); *see also United States v. PG&E*, No. 14-cr-175, 2015 WL 3958111, at *7-8 (N.D. Cal. June 29, 2015); Mot. 23-24 (citing additional cases).

II. The Government Must Produce the Requested Materials.

The government also argues that it need not produce the requested documents under Rule 16 on the grounds that (a) they are not material, (b) searching for them would be overly burdensome, and (c) with respect to the SEC agent notes, the documents are shielded by work product privilege. These arguments fail.

A. The Requested Documents Are Material to the Defense.

As the government recognizes, Ms. Holmes need only make "a prima facie showing of materiality" under Rule 16. Opp'n 10. That threshold showing is a minimal one. *See United States v. Stever*, 603 F.3d 747, 752-53 (9th Cir. 2010); *see also* Mot. 8-9 (citing cases). Evidence—whether inculpatory or exculpatory—is "material" for Rule 16 purposes if it is "helpful" to crafting a defense. *E.g.*, *Stever*, 603 F.3d at 752 (internal quotation marks omitted). The government did not dispute materiality during the parties' meet-and-confer process, *see* Mot. 7-8, and its submission of Ms. Holmes' requests to the subject agencies is a tacit admission that the requests seek material documents.

In its opposition, however, the government argues that two of the categories related to FDA and CMS—those relating to agency communications with Wall Street Journal reporter John Carreyrou (Category 1) and those relating to agency communications with clinical laboratory companies (Category 3)—are not material. The government asserts that both categories improperly "rel[y] on assumptions" and are not relevant to the charged conspiracies. Opp'n 10. It is wrong on both fronts.

First, the requests in Categories 1 and 3 are not based on "assumptions," but are based on the government's own productions of documents from these agencies and interviews with their employees.

See Mot. 14-16, 18-19; Mot. Exs. 1, 9, 10, 11, 12, 13, 14, 15, 16. In her motion, Ms. Holmes identified concrete evidence of the agencies' interactions with (and influence by) the press or Theranos' competitors, including but not limited to: (1) internal CMS communications showing that contact from Carreyrou spurred the agency to action on a complaint, Mot. Ex. 9; (2) an internal FDA briefing memo indicating that contact from Carreyrou prompted the 2015 inspection of Theranos, Mot. Ex. 10; and (3) an internal FDA email chain regarding steps that should be taken in response to a confidential complaint filed by Quest Diagnostics, Inc., Mot. Ex. 16. Additional evidence demonstrates the existence of responsive agency documents:

- FDA employee Seema Singh told government investigators that the 2015 Theranos inspection was based on a complaint, details of which were the same as those in the *Journal* articles. Ex. 1 (excerpt of FDA interview memorandum of Seema Singh). "Her supervisor, Eric Anderson, told her the information about the [*Journal*] article, and she probably read the article before she went in to inspect." *Id.*

- Several FDA employees have stated that the circumstances around the 2015 Theranos inspection were "unusual." FDA employee Alberto Gutierrez noted that the inspection was "unusual" in that subject matter experts were sent alongside field investigators, which normally is not the case, and because so many people went to the inspection. Ex. 2 (excerpt of FDA interview memorandum of Alberto Gutierrez). FDA compliance employee Sergio Chavez was involved even before the inspection occurred. He noted that "[w]ith the Theranos inspection, there was something unusual early on before the inspection even began," and that it appeared "someone wanted to make sure that if the inspection went down a route where enforcement action was needed, then there'd be a compliance officer involved early on." Ex. 3 (excerpt of FDA interview memorandum of Sergio Chavez).

- CMS employee Gary Yamamoto conceded that the CMS Central Office's involvement in the 2015 survey also was "unusual." Ex. 4 (excerpt of FDA interview memorandum of Gary Yamamoto). CMS employee Sarah Bennett reported similarly. Ex. 5 (excerpt of FDA interview memorandum of Sarah Bennett) (stating it was "unusual" CMS central office personnel attended Theranos inspection). Theranos employee Sunil Dhawan reported that Yamamoto had spoken to the media before the inspection: "During an initial meeting before the [September 2015] audit started, the San Francisco based CMS inspector [Yamamoto] discussed Theranos press releases and calls he had received from the media. Dhawan believed the inspector was troubled by this." Ex. 6 (excerpt of U.S. Postal Inspection Service interview memorandum of Sunil Dhawan).

In short, the record shows the following: Carreyrou was in contact with employees at both FDA and CMS regarding Theranos; Carreyrou-cultivated sources submitted complaints to the agencies that prompted inspections; Carreyrou encouraged at least one other Theranos source to file a similar complaint; agency personnel concede that they were motivated to inspect Theranos at least in part by the

media focus on company; and multiple employees of both agencies noted that the inspections were unusual in their procedural aspects and in the degree of scrutiny exerted at the outset. The record also reveals that at least one Theranos competitor—Quest—was also working behind the scenes to train these agencies' focus on the company.

The government has produced a dearth of documents bearing on these issues, apparently because it does not believe documents responsive to these categories are even relevant to the case. *See* Opp'n 10-11; *see also* Opp'n Ex. C (asserting that this category of documents is not relevant to the case). The government is wrong here too. Evidence of bias or procedural irregularities in the regulatory inspections that set in motion the collapse of Theranos go to the heart of the government's case. There can be no doubt that the government will seek to point to the results of those inspections as proof of the charged fraudulent scheme; why else would it produce reams of documents relating to the results of these inspections? The requested documents thus are not analogous to those requested in *United States v. Armstrong*, 517 U.S. 456 (1996), cited by the government, which held that Rule 16(a)(1)(C) does not authorize discovery in support of a motion to dismiss a case for selective prosecution. *Id.* at 462; *see* Opp'n 10-11. Here, the requested documents undermine key evidence that the government will offer at trial and thus are "evidence relevant to the government's case in chief." Opp'n 10.

B. The Requests Are Not Burdensome.

The government's argument that compliance with the motion is too burdensome relies heavily on correspondence from the FDA and CMS. Opp'n 11 & Exs. C, D. But the gravamen of the agencies' burden argument is that they already spent significant resources providing documents helpful to the government. *See* Opp'n Ex. C at 1 ("Moreover, as you know, the Department of Justice ("DOJ") previously received from FDA . . . a significant number of FDA documents–over 40,000 pages–relating to Theranos, ..."); Ex. D at 1 ("CMS has already expended significant resources to identify, search, collect, and produce over 260,000 pages to DOJ in this litigation . . . ."). The extent of the agencies' cooperation with the government to build its case against Ms. Holmes cannot possibly diminish their obligation to produce the much smaller subset of documents requested by Ms. Holmes. In fact, the controlling cases hold just the opposite; the agencies' extensive prior compliance with the government's

requests is why justice demands that the documents requested by Ms. Holmes be produced in the first place. *See* pp. 1-3, *supra*.

The agencies also point to a subpoena from Mr. Balwani in the SEC case as exacerbating this purported burden. Opp'n Ex. C at 2; Ex. D at 1. But if the agencies are correct that the SEC subpoena covers many of the same documents (something that Ms. Holmes has no basis to evaluate as a non-party to the SEC case),[2] then the incremental burden of complying with Ms. Holmes' requests should be minimal.

The agencies' generic complaints about the burdens of compliance cannot overcome their obligations to produce the narrow categories of documents that Ms. Holmes requested. In fact, neither the government nor the agencies tailor their generic burden arguments to Ms. Holmes' actual requests. Generic, unsupported arguments that compliance is burdensome do not suffice. *See United States v. Mandel*, 914 F.2d 1215, 1219 (9th Cir. 1990) (interests of government weighed against materiality only where "government ***has shown*** that complying with the request would be unduly burdensome" (emphasis added)).

C. The Government Must Produce SEC Notes of Interviews of Craig Hall and Bryan Tolbert.

The government narrows its opposition to Category 5 to resisting production of SEC agent notes and interview memoranda on the grounds that they contain work product and are otherwise non-discoverable under Rule 16(a)(2). Opp'n 12-13. The government offers instead to do what the law already requires—review SEC agent notes of witness interviews for *Brady* material. Opp'n 13. The government's blanket invocation of work product protection ignores that Category 5 also seeks documents such as communications between the agency and potential witnesses that by definition do not contain attorney work product. *See* Mot. 2. Though Ms. Holmes disagrees with the government that documents responsive to Category 5 are not producible under Rule 16 for that and other reasons, she accepts the government's offer to conduct a *Brady* review of SEC agent notes as satisfaction of her

[2] As explained in Part III, *infra*, the agencies' reliance on the terms and search protocols negotiated in a case in which Ms. Holmes is not a party renders their offer of voluntary compliance inadequate to satisfy Ms. Holmes' Rule 16 and constitutional rights in this separate criminal proceeding.

request in this category pending the results of that review, with one exception: the government should be required to produce SEC agent notes and interview memoranda of the interviews of Craig Hall and Bryan Tolbert. For these witnesses, Ms. Holmes has already made a particularized showing that *Brady* material exists in SEC files because Mr. Hall either lied to the government when he said that he recorded the December 2013 Theranos investor call, or lied under oath in his deposition in the SEC case. Mot. 21. The notes and memoranda of Mr. Hall's interview are favorable under *Brady* either way and must be produced. *See United States v. Park*, 319 F. Supp. 2d 1177, 1179 (D. Guam 2004) (granting motion to compel agent interview notes under *Brady*). Moreover, the circumstances of Mr. Tolbert's recent deposition indicate that SEC notes of that interview likely contain *Brady* material. *See* Mot. 21 n.19. The government must also produce SEC communications with these witnesses and/or their counsel, such as emails and other correspondence. *See United States v. Singhal*, 876 F. Supp. 2d 82, 105 (D.D.C. 2012); *United States v. Sudikoff*, 36 F. Supp. 2d 1196, 1206 (C.D. Cal. 1999).

III. The Government's Offer Is Inadequate.

In the end, the government pleads that a Court order is unnecessary because certain of the agencies have agreed to make "reasonable document productions in response to the pending requests made voluntarily by the government." Opp'n 11. But Ms. Holmes is entitled to more than what the agencies view as "reasonable document productions." She is entitled to a document production that complies with Rule 16 and the Constitution, to enable her to develop and present a complete defense. *See Crane v. Kentucky*, 476 U.S. 683, 690 (1986).

A. The Government's Pattern of Delay.

The fact that the parties' dispute over these documents remains unresolved almost six months after Ms. Holmes' initial request is a consequence of the government's extraordinary delay. The following timeline shows the key dates in the parties' exchange, *see* Mot. 7-8 & Mot. Ex. 5:

Date	Event
February 5, 2019	Ms. Holmes first writes to the government requesting certain agency materials under Rule 16 and *Brady*.
February 8, 2019	Ms. Holmes supplements her requests for agency documents.

February 22, 2019	The government responds that the agency documents are not producible under Rule 16 or *Brady* because the agencies are not part of the "prosecution team."
March 27, 2019	Ms. Holmes replies to the government's flawed "prosecution team" argument, reiterates demand for documents, and requests a meet and confer.
April 1, 2019	The parties meet and confer. The government refuses to produce any documents.
April 5, 2019	At the government's request, the parties meet and confer again. The government offers to submit Ms. Holmes' requests to the agencies on a voluntary basis.
April 7, 2019	The defense informs the government that it will seek a Court order compelling production.
April 15, 2019	Ms. Holmes files the motion to compel.
April 22, 2019	At a status conference before the Court, the defense consents to the government's request for a stay in the briefing schedule so that the government may work with the agencies potentially to comply with Ms. Holmes' requests. The parties agree they will update the Court by mid-May.
May 9, 2019	The parties meet and confer about the status of the government's discussions with the agencies. **The government reports that it had not submitted Ms. Holmes' requests to the agencies until earlier that day.** The government asks the defense for additional time to allow the agencies to consider the requests.
May 17, 2019	The parties schedule a follow-up call to discuss the status of the government's discussions with the agencies. The call is cancelled when the government reports that there is nothing to update.
May 24, 2019	The parties submit a joint status report to the Court indicating that the agencies had not yet provided a response and setting a briefing schedule for the motion. *See* ECF No. 75.
June 10, 2019	The government provides Ms. Holmes with written responses from the FDA, CMS, and CDPH.
June 15, 2019	The government files its opposition brief.

The government's offer of voluntary production invokes the language of reasonableness, but that language must be viewed in the context of its actions detailed above. In particular, although the government first offered to provide the agencies with Ms. Holmes' requests on April 5, 2019, it was not

until ***over a month later*** on May 9, 2019 that it actually did so. And that submission to the agencies occurred ***over two weeks after*** the status conference before the Court where the government sought relief from filing its opposition so that it could work with the agencies (the submission also happened to occur on the morning of the day when the defense had requested an afternoon meet and confer). The agencies' responses arrived over two months after the government first floated the offer to Ms. Holmes, and just shy of six months after her initial request. As a result, Ms. Holmes is nowhere closer to obtaining these documents that she needs to prepare her defense (and to which she is entitled under Rule 16) than she was almost half a year ago. The government still does not commit to a firm date by which Ms. Holmes can expect the documents, and its protestations of burden suggest that any voluntary compliance may be intolerably slow. Only a Court order can ensure that Ms. Holmes receives the documents in sufficient time to prepare her defense.

B. A Court Order Is Necessary To Prevent Further Delay and Incomplete Productions.

As to the SEC, the government asserts that the SEC will produce no documents responsive to Ms. Holmes' requests absent an order from this Court. With respect to FDA, CMS, and CDPH, although those agencies' letters volunteering to make "reasonable" productions are hopelessly vague, it is clear that they intend to produce less than what Ms. Holmes has requested. Their responses are insufficient or incomplete in at least the following ways that demonstrate the need for a Court order:

Limiting Productions to the Balwani SEC Subpoena. The FDA limits the documents it will voluntarily produce to those subject to a subpoena served by Mr. Balwani in the SEC case. *See* Opp'n Ex. C at 2. CMS similarly limits its production for Category 4 to those it has or soon will produce in the SEC case. Opp'n Ex. D at 3. But Ms. Holmes is not a party to the SEC case, she had no role in negotiating the limitations on the scope of those requests, and she thus lacks the information necessary to evaluate whether and to what extent the civil subpoena overlaps with her six requests. The June 7 and 10 letters from FDA and CMS included with the government's opposition offer only vague descriptions of the scope of what these agencies will determine unilaterally to collect and produce, and when they plan to produce it. The FDA, for example, disputes that certain categories of documents requested by Ms. Holmes—including, notably, all documents relating to FDA contact with Carreyrou—are even

relevant. Opp'n Ex. C at 2. Given that assertion, Ms. Holmes has no idea whether the FDA's production in the SEC case will capture those documents; the FDA has given this Court no reason to believe that it will. Both the FDA and CMS appear to have chosen a set of custodians and search terms, but they have provided no information to Ms. Holmes (or the Court for that matter) that would suggest that the custodians and search terms will capture Ms. Holmes' requests. *See* Opp'n Ex. C at 2 ("To respond to the subpoena, FDA has already searched the records of at least 45 custodians, . . . and has collected in excess of 62,000 documents that contain the keywords for which we searched."); Ex. D at 2 (limiting production responsive to category 2 to "CLIA group communications" without defining terms); *id.* ("CMS identified . . . external communications between additional CMS custodians selected by Mr. Balwani and Theranos . . . ."). This is Ms. Holmes' motion—not Mr. Balwani's—and this is not a civil enforcement case governed by the Federal Rules of Civil Procedure. Ms. Holmes cannot agree to accept a civil production of unidentified scope in lieu of compliance with her limited requests for material documents.

Vague Privilege & Confidentiality Assertions. The FDA cites a laundry list of privilege and confidentiality limitations on its productions, including those implicating Theranos' and third-parties' trade secrets and confidential commercial or financial information, personal privacy information, investigatory files, deliberative process, and other unspecified protected information. Opp'n Ex. C at 3. It also states that it will produce versions of documents previously redacted under the Freedom of Information Act ("FOIA"). *Id.* Many of these vaguely stated "privileges"—like those for "investigatory files" or "trade secrets"—are not legitimate grounds for refusing to produce documents under Rule 16. *See, e.g.*, *United States v. O'Keefe*, Crim. No. 06-249, 2007 WL 1239204, at *2 (D.D.C. Apr. 27, 2007) ("[C]oncerns about confidentiality and the privacy rights of others [cannot] trump the right of one charged with a crime to present a fair defense."). Other identified privileges—like the deliberative process privilege—are qualified and can be overcome if the documents are material to the defense. *See, e.g.*, *United States v. Trabelsi*, Crim. No. 06-89, 2015 WL 51575882, at *6 (D.D.C. Sept. 3, 2015).[3]

[3] Moreover, the statutes the FDA cites do not justify withholding trade secret and/or confidential information in this criminal case. 21 C.F.R. § 20.61 relates to FOIA requests and thus has no applicability here. Similarly, 21 U.S.C. § 360j(c) has been held to offer no protection from disclosure beyond that provided by FOIA and concerns only routine nondisclosure of trade secrets. *Anderson v.*

And the FDA has waived whatever deliberative process privileges it could assert regarding the Theranos documents by producing numerous internal communications among FDA employees discussing Theranos. *See* Wade Decl. ¶ 4. The FDA cannot be permitted to invoke the deliberative process privilege only when doing so would shield documents unhelpful to the government's case.

The FDA's previewing of these coming roadblocks to any voluntary production underscores the need for a Court order. If the Court orders production, then the FDA could not rely on statutes or internal policies that limit voluntary release of agency documents in the ordinary course of business; rather, the government would have to establish privilege on a document-by-document basis. *See, e.g.*, *United States v. Perez-Madrigal*, No. 16-CR-20044, 2017 WL 2225221, at *10 (D. Kan. May 19, 2017) (government "bears burden of establishing applicability of [a] privilege" in response to valid Rule 16 request). Without a Court order, the FDA would be able to withhold responsive documents on its own say-so, and Ms. Holmes would have no mechanism for contesting the applicability of the claimed limitation. Eventually, Ms. Holmes would have to file individual motions to compel documents (or portions of documents) that are missing from the rolling productions, if it would even be possible to determine what the agency unilaterally decided to withhold. The Court should preempt this unworkable process that would interfere with Ms. Holmes' preparation for trial by granting the motion.

Purporting to Determine What Is "Relevant" to the Case. The FDA—which is not a party to this case—asserts that none of the documents other than those in Category 4 are "relevant" to the case. Opp'n Ex. C at 2.[4] That is not the FDA's determination to make. Absent a Court order, it is completely unclear whether the FDA will produce documents responsive to the other categories.

CDPH's Missing Notes. CDPH responds to Ms. Holmes' request by representing that only eight

HHS, 907 F.2d 936, 950 (10th Cir. 1990). And, as the FDA concedes, the Trade Secrets Act merely prohibits FDA from releasing qualifying information "unless otherwise authorized by law." Opp'n Ex. C at 3; *see Anderson*, 907 F.2d at 950 (Trade Secrets Act "is merely a general prohibition against unauthorized disclosure"). Of course, a Court order would make production "authorized by law." Ms. Holmes is willing to discuss with the agencies the terms of a protective order to allay any concerns about preserving confidentiality as to third parties for documents produced under a Court order.

[4] Although the CMS letter is less combative in tone, it similarly hints that its judgment about what is relevant to Ms. Holmes' defense will shape its compliance with her requests. See Opp'n Ex. D at 3 ("CMS already produced to DOJ the ***relevant*** documents pertaining to the 2013 Theranos CLIA survey that CMS could pull from its system." (emphasis added)).

total documents remain in its possession regarding the 2013 CLIA inspection of Theranos. Opp'n Ex. E. It also states also notes of that inspection are "no longer available." *Id.* These representations suggest that evidence critical to Ms. Holmes' defense may have been destroyed and raises questions about the circumstances of the notes' disposal. The Court should order CDPH's compliance with the motion so that a complete production may reveal the full extent of its remaining documentation surrounding the 2013 CLIA inspection.

* * *

The above gaps between what Ms. Holmes is entitled to under the law and what the government has agreed to produce voluntarily demonstrate the inadequacy of its offer. But they also preview the many ways that a voluntary production will lead to further disputes and further delay. Ms. Holmes has been requesting these documents for almost half a year. Only a Court order will clear the way for a full, expeditious production.

CONCLUSION

For the foregoing reasons, and those set forth in the motion, the Court should enter an order compelling production of the requested materials under Rule 16 and *Brady*.

DATED: June 24, 2019

Respectfully submitted,

/s/ Lance Wade
KEVIN DOWNEY
LANCE WADE
Attorneys for Elizabeth Holmes

JOHN D. CLINE (CA State Bar No. 237759)
One Embarcadero Center, Suite 500
San Francisco, CA 94111
Telephone: (415) 662-2260 | Facsimile: (415) 662-2263
Email: cline@johndclinelaw.com

KEVIN M. DOWNEY (Admitted Pro Hac Vice)
LANCE A. WADE (Admitted Pro Hac Vice)
SEEMA MITTAL ROPER (Admitted Pro Hac Vice)
MICHELLE CHEN (Admitted Pro Hac Vice)
WILLIAMS & CONNOLLY LLP
725 Twelfth Street, NW
Washington, DC 20005
Telephone: (202) 434-5000 | Facsimile: (202) 434-5029
Email: KDowney@wc.com; LWade@wc.com; SMRoper@wc.com; MChen@wc.com

Attorneys for Defendant ELIZABETH A. HOLMES

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. ELIZABETH HOLMES and RAMESH "SUNNY" BALWANI, Defendants.	Case No. CR-18-00258-EJD **DECLARATION OF LANCE WADE IN FURTHER SUPPORT OF MS. HOLMES' MOTION TO COMPEL PRODUCTION OF RULE 16 DISCOVERY AND *BRADY* MATERIALS** Date: June 28, 2019 Time: 10:00 a.m. CTRM: 4, 5th Floor Hon. Edward J. Davila

I, LANCE WADE, declare as follows:

1. I represent Defendant Elizabeth Holmes and have been admitted to practice *pro hac vice* in the above-captioned matter. I submit this declaration in support of Ms. Holmes' Reply in Further Support of Ms. Holmes' Motion To Compel Production of Rule 16 Discovery and *Brady* Materials (the "Reply"). I attest to the following facts upon which the Reply relies:

2. On May 9, 2019, the parties met and conferred by telephone regarding the status of the

government's discussions with the agencies. The government reported on this call that it had provided the FDA and CMS with Ms. Holmes' requests earlier that same day. The government asked that the defense allow time for the agencies to consider the requests.

3. The parties scheduled a follow-up call for May 17, 2019. The call was cancelled when the government notified the defense that there was no new information to report.

4. The government's Rule 16 productions in this case contain numerous internal communications among FDA employees relating to Theranos. The undersigned has reviewed a set of these communications containing internal agency deliberations regarding regulatory actions concerning Theranos. The defense can provide these documents upon the Court's request.

5. Attached to the Reply are 6 exhibits containing copies of documents produced as discovery in this case. The contents of each are as follows:

a. Exhibit 1 is a true and correct copy of an excerpt of an FDA memorandum of a December 12, 2017 interview of Seema Singh of FDA.

b. Exhibit 2 is a true and correct copy of an excerpt of an FDA memorandum of a September 13, 2017 interview of Alberto Gutierrez of FDA.

c. Exhibit 3 is a true and correct copy of an excerpt of an FDA memorandum of a December 14, 2017 interview of Sergio Chavez of FDA.

d. Exhibit 4 is a true and correct copy of an excerpt of an FDA memorandum of a December 12, 2017 interview of Gary Yamamoto of CMS.

e. Exhibit 5 is a true and correct copy of an excerpt of an FDA memorandum of a September 12, 2017 interview of Sarah Bennett of CMS.

f. Exhibit 6 is a true and correct copy of an excerpt of a U.S Postal Inspection Service memorandum of a June 22, 2017 interview of former Theranos employee Sunil Dhawan.

6. All exhibits have been redacted to omit personal identifying information as well as information not relevant to the motion.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct to the best of my knowledge.

Executed this 24th day of June in Washington, D.C.

LANCE WADE
Attorney for Elizabeth Holmes

Exhibit 1

Food and Drug Administration
OFFICE OF CRIMINAL INVESTIGATIONS
MEMORANDUM OF INTERVIEW

CASE NUMBER:	2016-MWM-709-0576
CASE TITLE:	THERANOS, INC.
DOCUMENT NUMBER:	261286
PERSON INTERVIEWED:	Seema Singh, FDA
PLACE OF INTERVIEW:	USAO, San Francisco
DATE OF INTERVIEW:	12/12/2017
TIME OF INTERVIEW:	1200 PST
INTERVIEWED BY:	SA George Scavdis
OTHER PERSONS PRESENT:	See below.

On 12/12/2017, the case agent interviewed Seema Singh, investigator, FDA, regarding an inspection she conducted of Theranos, Inc. in 2015. Also present during the interview were the following: AUSA Jeffrey Schenk, United States Attorney's Office for the Northern District of California (USAO/NDC); AUSA John Bostic, USAO/NDC; Mario Scussel, Federal Bureau of Investigation; Christopher McCollow, U.S. Postal Inspection Service; Mark Katz, Securities and Exchange Commission; and Kelsey Schaefer, FDA, Office of the Chief Counsel (telephonically).

Singh started with FDA in 2010 as an investigator. She conducted food inspections for six months, and then she went directly into inspections of medical device manufacturers. She is now a medical device specialist, and her background is in engineering. Singh is assigned high priority cases and inspections, and she only does medical device inspections. She said that the exact definition of what a medical device is would be stated in the Federal Food Drug and Cosmetic Act. Singh has had no interaction with anyone from Theranos since FDA's inspection in 2015.

If a company registered as a medical device manufacturer, or if they haven't registered and there's some complaint, then FDA will go out and evaluate the device the company manufactures and determine if what they're looking at is truly a medical device; this is how FDA knows whether to send in Singh to inspect. Any registration listing issues go to FDA's Center for Devices and Radiological Health (CDRH). Singh collects evidence during an inspection, and that evidence goes to CDRH (the Center), who then makes the final decision on what regulatory actions, if any, to take. Sometimes that decision is to convene a regulatory meeting between FDA and the company, and sometimes that decision is to issue a Warning Letter. The company is not always notified in the same manner that what they are manufacturing is deemed by FDA to be a medical device.

Singh had done a lot of inspections before being assigned the Theranos inspection. She estimated that she had conducted roughly one inspection per month since 2010. Prior to conducting an inspection, she researches the following: the registration listing, locations the company has, products, product codes, adverse events for the device, inspectional history, and other devices the company manufactures. After that, she formulates a GMP (Good Manufacturing Practices) inspectional plan. The Theranos assignment was a For Cause inspection assignment. As an investigator, Singh doesn't typically say something is a safety concern; she focuses primarily on GMPs during an inspection. However, if there is a safety issue, she'll put that in her report for the Center to evaluate it. The Theranos For Cause inspection was based on a complaint.

Singh thinks the details of the complaint were the same as those that were detailed in the Wall Street Journal's article about Theranos. Her supervisor, Eric Anderson, told her the information about the Wall Street Journal article, and she probably read the article before she went in to inspect. Singh doesn't read too much on the Internet about a company because she doesn't want anything clouding her judgment when she does an inspection. In the case of Theranos, she didn't find anything about adverse events about their device in her pre-inspectional research.

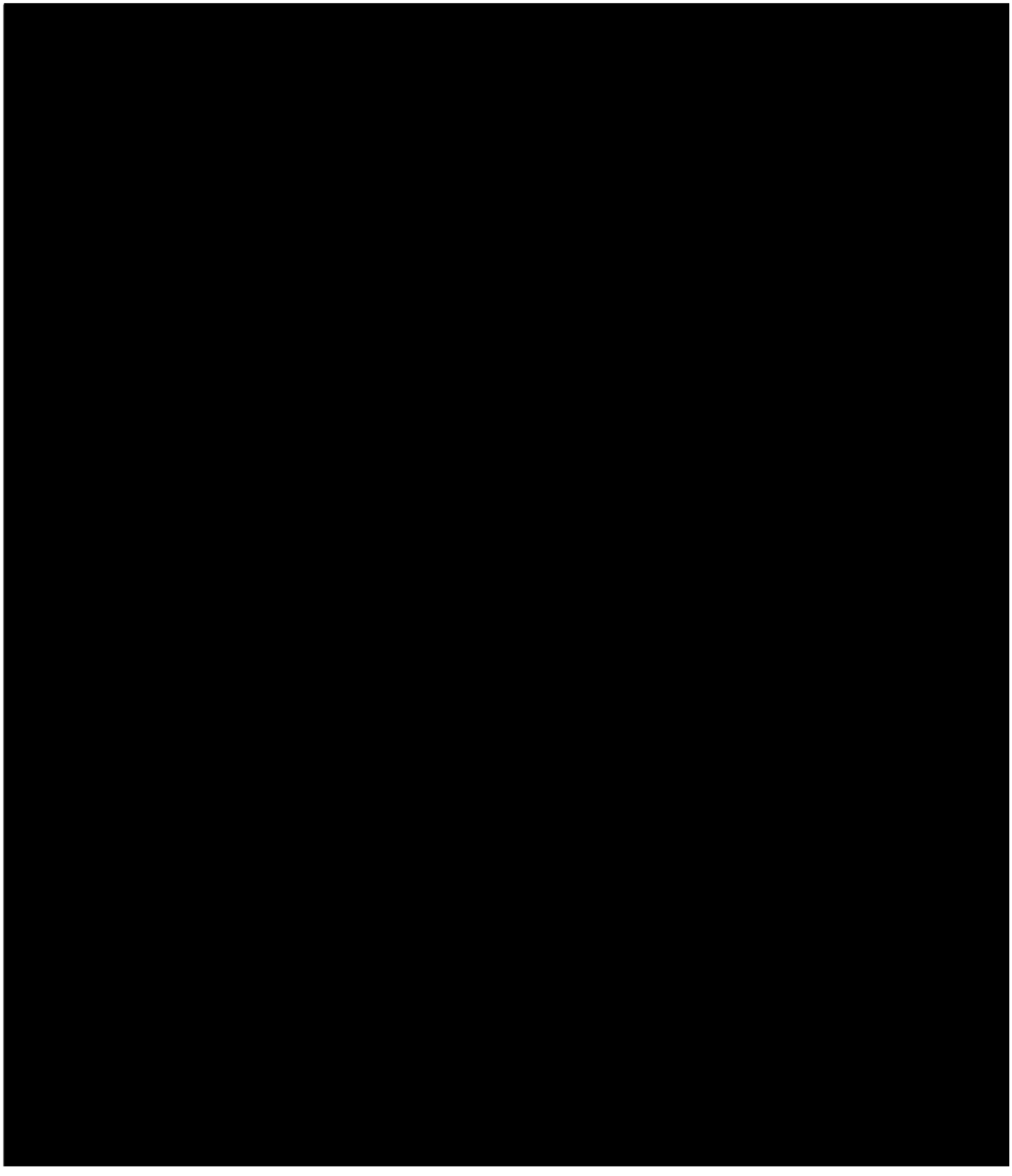

Exhibit 2

Food and Drug Administration
OFFICE OF CRIMINAL INVESTIGATIONS
MEMORANDUM OF INTERVIEW

CASE NUMBER:	2016-MWM-709-0576
CASE TITLE:	THERANOS, INC.
DOCUMENT NUMBER:	258748
PERSON INTERVIEWED:	Alberto Gutierrez, CDRH, OIR
PLACE OF INTERVIEW:	FDA White Oak, Silver Spring, MD
DATE OF INTERVIEW:	09/13/2017
TIME OF INTERVIEW:	1230 EST
INTERVIEWED BY:	SA George Scavdis
OTHER PERSONS PRESENT:	See below.

On September 13, 2017, the case agent interviewed Alberto Gutierrez, Director of FDA's Office of In Vitro Diagnostics and Radiological Health (OIR), regarding his interactions with Theranos, Inc. Also present during the interview were the following: AUSA Jeffrey Schenk, United States Attorney's Office for the Northern District of California; Jessica Chan, Securities and Exchange Commission (SEC), Division of Enforcement (DOE); Rahul Kolhatkar, SEC, DOE; Monique Winkler, SEC, DOE; and Kelsey Schaefer, FDA, Office of the Chief Counsel (OCC).

[redacted]

FDA was already concerned with the data for the Nanotainers. After that, two things happened that made it easier for FDA to inspect Theranos. First, Theranos received clearance for its HSV-1. Ironically, this made it easier for FDA to inspect Theranos because it made it harder for Theranos to claim they were an LDT, given that they had just received a device clearance. Second, around the summer of 2015, FDA heard from a reporter from the Wall Street Journal about their concerns regarding Theranos. A Wall Street Journal reporter made a request through FDA's Public Affairs Office, and Gutierrez eventually spoke to him on at least two occasions. Ultimately though, it was the issues in Theranos's data that were the impetus for the inspection. Even before being approached by the Wall Street Journal, FDA already had concerns that were obvious from the data they were seeing.

Normally, either ORA (Office of Regulatory Affairs) or the field conducts FDA inspections. ORA can request a directed inspection and the field then decides when they go in. In this case, ORA sent SMEs (subject matter experts) to inspect Theranos alongside investigators from the field, which was unusual. This was requested by Gutierrez, and he was the one who made the decision to inspect. Gutierrez asked the field to provide investigators, and he decided who from ORA went as SMEs. Gutierrez again noted that this is unusual. The inspection request occurred in December 2014 or in January 2015. Ian Pilcher was going to go and do the inspection, but ORA didn't proceed quickly enough. Inspections are not normally done prior to clearing a 510(k). The fact that Theranos had one test that was working (HSV-1) doesn't mean FDA couldn't go forward with an inspection; the two are unrelated.

Gutierrez chose Pilcher as one of the SMEs to inspect Theranos because he's a very good inspector and because he's worked in industry. When Shuren was suggesting that FDA send someone out to Theranos to help them put their data together, Pilcher is who Gutierrez would have sent. Turning back to that suggestion by Shuren, Gutierrez remarked that it was an unusual request. It would have put that FDA employee in a weird position. Gutierrez was concerned by the request, and he wanted to do it through a more formal means. That's why he ordered the inspection.

FDA rarely sends as many people out on an inspection as it did with Theranos. Prior to the inspection, FDA would have had internal pre-inspection meetings. FDA was interested in figuring out whether Theranos was using their instrument, whether they were using it in all their laboratories, and exactly what they were doing. Gutierrez was in communication with the inspection team every day, as they would call to give him updates. It's not atypical on an inspection like this to do a debriefing every day. The inspection team told Gutierrez

that Theranos wasn't being responsive in giving documentation. Gutierrez doesn't recall if he talked to Holmes to try to rectify that. There was a lot going on at that time. Their lawyers called FDA and there was back and forth between FDA and Theranos where Theranos was challenging FDA's authority to inspect. Gutierrez didn't speak to anyone else from Theranos aside from Daniel Krakov. Gutierrez doubts anyone from FDA reached out to Holmes to get Theranos to be more responsive in providing documents.

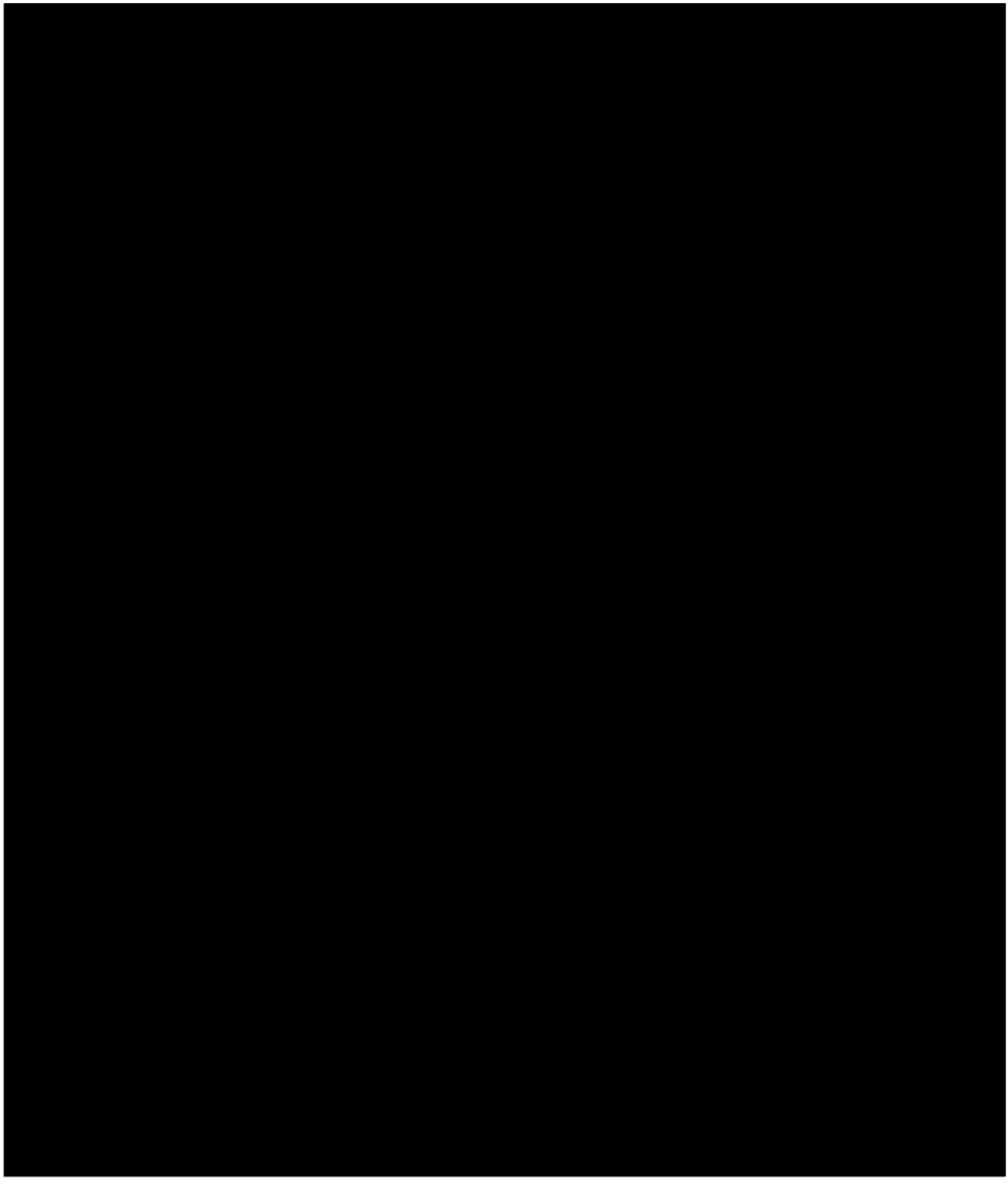

Exhibit 3

Food and Drug Administration
OFFICE OF CRIMINAL INVESTIGATIONS
MEMORANDUM OF INTERVIEW

CASE NUMBER:	2016-MWM-709-0576
CASE TITLE:	THERANOS, INC.
DOCUMENT NUMBER:	261615
PERSON INTERVIEWED:	Sergio Chavez, FDA
PLACE OF INTERVIEW:	USAO, San Francisco, CA
DATE OF INTERVIEW:	12/14/2017
TIME OF INTERVIEW:	1130 PST
INTERVIEWED BY:	SA George Scavdis
OTHER PERSONS PRESENT:	See below.

On 12/14/2017, the case agent interviewed Sergio Chavez, compliance officer, FDA, regarding an inspection FDA conducted of Theranos, Inc. in 2015. Also present during the interview were the following: AUSA Jeffrey Schenk, United States Attorney's Office for the Northern District of California (USAO/NDC); AUSA John Bostic, USAO/NDC; Mario Scussel, Federal Bureau of Investigation; Monique Winkler, Securities and Exchange Commission; and Kelsey Schaefer, FDA, Office of the Chief Counsel (OCC) (telephonically).

The only interactions Chavez ever had with anyone from Theranos was at a regulatory meeting, which was held in the San Francisco District Office. Elizabeth Holmes was at that meeting, which was memorialized in meeting minutes (attachment one), and that's the only time Chavez ever saw or spoke to her. His only communications with Theranos prior to this meeting were e-mail communications that facilitated the meeting.

Chavez described his role during the Theranos inspection in 2015 as being in the background while communicating with the investigators and providing them with justification for being at the inspection. He was providing them guidance, which is part of the job of a compliance officer. Questions come up from investigators all the time during inspections, and compliance officers help them answer those questions. Later, during case development, the compliance officers look at what was collected during an inspection, and then formulate recommendations on what action FDA should take. Chavez has degrees in physiology and chemistry. He worked in industry on drug delivery devices, and he worked in laboratories testing those devices. He started at FDA as an investigator, and conducted medical device inspections for four or six years. He's been a compliance officer for seven years. He's had FDA legal training, but if there's legal questions about FDA's jurisdiction, he'll seek advice from FDA/OCC. Regarding FDA's jurisdiction to inspect Theranos in 2015, Chavez recalls that the issue was already decided when the inspection assignment was made. There were letters from FDA to Theranos informing them of FDA's opinion. The arguments made by Theranos's lawyers that FDA didn't have jurisdiction to inspect were just "fluff" and were an attempt to intimidate the FDA investigators.

Chavez explained that, for him to get involved in an inspection, an investigator will first contact the investigator's supervisor, and then that supervisor will say something to Chavez's supervisor, and then it gets to Chavez. With the Theranos inspection, there was something unusual early on before the inspection even began. Chavez recalls getting e-mails informing him that individuals from the Center for Devices and Radiological Health (CDRH) would be coming out to Chavez's district, so someone thought it would be good to have a compliance officer at those meetings. Chavez doesn't recall what the anticipated issues were.

AUSA Schenk showed Chavez a copy of an e-mail dated 08/26/2015, titled "Bullet points for Theranos inspection." (Attachment two) Lawton Lum is Chavez's supervisor. Chavez said somebody other than him anticipated the issues detailed in this e-mail, and that someone wanted to make sure that if the inspection went down a route where enforcement action was needed, then there'd be a compliance officer involved early on. At this point during the inspection, Chavez knew there were issues, and there were calls exchanged between investigators and CDRH. He listened in on some of the calls. At this point, there was no case for him to work--he was just listening. He gets materials to review after the EIR (Establishment Inspection Report) is finished. It's not unusual for him to be brought in early though. He explained that investigators need help, and things can get complicated. The Theranos inspection was complicated because the company lawyered up early on, and CDRH sent out SMEs (subject matter experts) for the inspection. Part of him talking with the investigators was to reassure them as to why they could be there and to inform them as to what they could ask for while they were there.

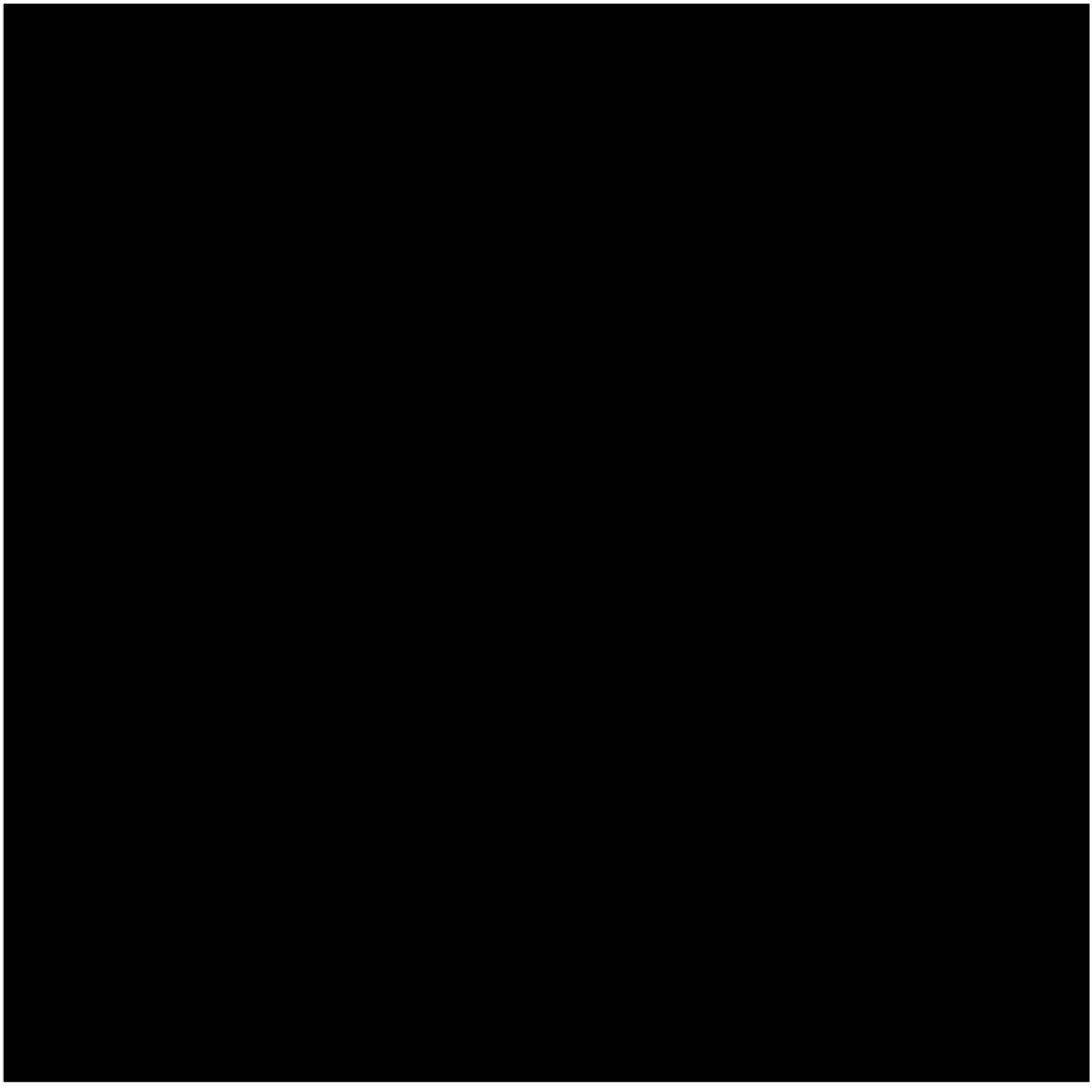

Exhibit 4

Food and Drug Administration
OFFICE OF CRIMINAL INVESTIGATIONS
MEMORANDUM OF INTERVIEW

CASE NUMBER:	2016-MWM-709-0576
CASE TITLE:	THERANOS, INC.
DOCUMENT NUMBER:	261269
PERSON INTERVIEWED:	Gary Yamamoto, CMS
PLACE OF INTERVIEW:	USAO, San Francisco, CA
DATE OF INTERVIEW:	12/12/2017
TIME OF INTERVIEW:	0900 PST
INTERVIEWED BY:	SA George Scavdis
OTHER PERSONS PRESENT:	See below.

On 12/12/2017, the case agent interviewed Gary Yamamoto, State Oversight and CLIA Branch, Division of Survey and Certification, Centers for Medicare & Medicaid Services (CMS), regarding a survey he conducted of Theranos, Inc. in 2015. Also present during the interview were the following: AUSA Jeffrey Schenk, United States Attorney's Office for the Northern District of California (USAO/NDC); AUSA John Bostic, USAO/NDC; Cameron Purves, Federal Bureau of Investigation; Christopher McCollow, U.S. Postal Inspection Service; Mark Katz, Securities and Exchange Commission; and Melissa Manson, Health and Human Services, Office of the General Counsel.

Yamamoto participated in a survey of Theranos's California laboratory in 2015, and he worked with Sarah Bennett (Survey and Certification Group, Center for Clinical Standards and Quality, CMS) on a survey of Theranos's California and Arizona laboratories in 2016.

[redacted]

[redacted]

In 2015, a complaint was lodged with the State of New York regarding Theranos's proficiency testing. New York said that they forwarded the complaint to CMS, but Yamamoto's office never received the complaint. He's since seen the complaint, but he didn't have it prior to the survey. He was, however, aware of the complaint's existence prior to the survey. In 2015 there were a series of articles written about Theranos in the press, and by then a second certification survey had been performed by the State that was not remarkable in any way. By the time of the 2015 survey that Bennett and Yamamoto conducted, Theranos had already come up for their third certification survey. In addition to the complaint in New York, CMS had received a complaint from a Theranos employee regarding QC on other FDA approved systems Theranos was using in its laboratories and regarding issues with their proprietary system and issues with the competency of Theranos's personnel. Yamamoto believes that the complaint in New York was from a man, and the second complaint from the employee was from a woman. He also believes that the New York complaint was related to proficiency testing, whereas the second complaint by the employee had to do with quality issues at Theranos. It was the combination of this complaint, the articles written in the media, and the requirement that Theranos's laboratory be certified every two years that led CMS to send Yamamoto and Bennett to Theranos to inspect their laboratory in Newark, CA. The survey was both a certification survey and a complaint survey.

Bennett and Yamamoto did the 2015 survey as a team. He had not previously done a joint survey with someone from CMS's Central Office. It was unusual for a person from CMS's Central Office to come out and do a survey with him. A laboratory is required to do QC, meaning that the laboratory needs to run QC materials for every day patient test results are reported, and those quality control levels should have a certain test result. The laboratory must hit those ranges to ensure accuracy of the test system. With Theranos, there were issues of patient test results that were out of control (OOC) yet still being reported; this is something that poor laboratories do all the time. Good laboratories don't do that. Good laboratories make sure their QC is within range, and poor laboratories report results when they fail QC. There were issues with calibration and maintenance as well.

[redacted]

Exhibit 5

Food and Drug Administration
OFFICE OF CRIMINAL INVESTIGATIONS
MEMORANDUM OF INTERVIEW

CASE NUMBER:	2016-MWM-709-0576
CASE TITLE:	THERANOS, INC.
DOCUMENT NUMBER:	258754
PERSON INTERVIEWED:	Sarah Bennett, CMS/Division of Laboratory Services
PLACE OF INTERVIEW:	CMS, 7500 Security Blvd., Woodlawn, MD
DATE OF INTERVIEW:	09/12/2017
TIME OF INTERVIEW:	1000 EST
INTERVIEWED BY:	SA George Scavdis
OTHER PERSONS PRESENT:	See below

On September 12, 2017, the case agent interviewed Sarah Bennett, Centers for Medicare and Medicaid Services (CMS), regarding a CLIA (Clinical Laboratory Improvement Amendments) survey she conducted of Theranos, Inc.'s (Theranos) high complexity laboratory in 2015. Bennett is a medical technologist in CMS's Division of Laboratory Services (DLS). Also present during the interview were the following: AUSA Jeffrey Schenk, United States Attorney's Office for the Northern District of California; Jessica Chan, Securities and Exchange Commission (SEC), Division of Enforcement (DOE); Rahul Kolhatkar, SEC, DOE; Monique Winkler, SEC, DOE; Gary Williams, HHS, Office of the General Counsel (OGC); and Kelsey Schaefer, FDA, Office of the Chief Counsel (telephonically).

[redacted]

Bennett said that Yamamoto received a complaint from a former Theranos employee. Additionally, the State of New York received a complaint, which they said they sent to CMS; however, CMS said they never received that complaint, so nobody within CMS could track that down. CMS started its on-site survey of Theranos in September 2015, and it came back to finish the survey in November 2015. The survey was announced to Theranos ahead of time. During the survey, CMS found that Theranos had a lot of procedures that had been signed by their new laboratory director just a day or two before the start of the September survey.

CMS conducts biannual CLIA surveys of a laboratory; so, in 2015, Theranos was due to be surveyed. If a laboratory submits a new Form 116 because it has hired a new laboratory director or for some other reason, that fact would not trigger a CLIA survey. Typically, a recertification survey is conducted approximately six months before the expiration of a laboratory's CLIA certificate. If there's some extenuating circumstance, like with Hurricane Irma or Hurricane Harvey, surveys of affected laboratories won't be completed within the two-year time frame. If the state agency tries to schedule a survey and the laboratory gives them the run around, normally the state agency will notify the CMS regional office. The CMS regional office can take enforcement action, whereas the state cannot. They can continue to try and reschedule, and if the laboratory continues to refuse, CMS can cite them for refusing an inspection, which allows CMS to take certain enforcement actions. Bennett doesn't know if any of this happened with Theranos. The state agencies are agents of CMS; they are not CMS employees.

Bennett explained that it is unusual that CMS sent central office personnel (Bennett) out on the Theranos survey. With that being said, Bennett had experience as a surveyor and she was asked to go by her supervisor, Karen Dyer, the director of DLS. Bennett said that DLS is also known as the CLIA program. Bennett has conducted CLIA surveys for CMS on two other occasions. Normally, re-certification surveys are conducted by the state agency, but because of the media attention associated with Theranos, the decision was made to send Yamamoto and Bennett. John Carreyoru (a reporter for the Wall Street Journal) had been in contact with CMS about an article he was writing on Theranos. Carreyoru talked to Dyer about the article. He has never spoken with Bennett. The CMS regional office conducts federal jurisdictional surveys. For instance, the National Institute of Health would be surveyed by CMS's Philadelphia Regional Office. Also, federal surveyors would be responsible for surveying the Maryland state laboratory, for example. Bennett was a natural to ask to do the survey because she has survey experience, and she had done it twice before. Most of the people within DLS are not surveyors. CMS knew the day that FDA went in to inspect Theranos (in August 2015). Bennett thinks FDA notified Dyer, and that Dyer told Bennett. The FDA inspection played no role in CMS deciding to involve its central office in the Theranos survey. Surveys are not coordinated between FDA and CMS; the two agencies have different authorities and they look at different things. They have different regulations, standards, and requirements that they're looking at. For instance, FDA would have been looking at the manufacturing, and CMS would have been looking at the testing. Typically, a laboratory is not both a manufacturer and a laboratory conducting tests.

Exhibit 6

MEMORANDUM OF INTERVIEW

CASE NUMBER	:	2204323-MF
PERSON INTERVIEWED	:	Sunil Dhawan
PLACE OF INTERVIEW	:	Securities and Exchange Commission Office, San Francisco, CA
DATE OF INTERVIEW	:	June 22, 2017
TIME OF INTERVIEW	:	9:00 A.M.

On June 22, 2017, at the Securities and Exchange Commission (SEC) office located in San Francisco, CA, Sunil Dhawan (DHAWAN) was interviewed regarding his employment at Theranos. Present for the interview were SEC Staff Attorneys Jessica Chan, Marc Katz, and Monique Winkler, Assistant United States Attorney Robert Leach, U.S. Food and Drug Administration, Office of Criminal Investigations Special Agent George Scavdis, and me. Present as DHAWAN's counsel were Gregory Vega and Robin Traylor. DHAWAN was admonished before the interview began. The following is a summary of the information DHAWAN provided.

DHAWAN was present for the September 2015 CMS audit. Also present were BALWANI, GEE, Heather King (KING), a lab consultant, Theranos' outside counsel, and two CMS inspectors; one San Francisco based inspector and one Washington, D.C. based inspector. During an initial meeting before the audit started, the San Francisco based CMS inspector discussed Theranos press releases and calls he had received from the media. DHAWAN believed the inspector was troubled by this. The inspector's comments regarding these items were directed towards BALWANI and KING.

After the initial meeting, the group broke into two teams to meet with the CMS inspectors. The inspectors reviewed Theranos' quality assurance and quality control procedures. During the audit, DHAWAN waited and sat outside the room where the auditors were meeting. He asked numerous times if he was needed for anything and was told, "No." Eventually, DHAWAN left the building. The audit took place over a two to three day period.